

JAN 20 2012

510(k) SUMMARY**J. MORITA USA Inc.'s**

TORQTECH: Type: ST-DH, CA-DC, CA-DC-O, and CA-51F-O
K#103697

1. NAME OF DEVICE

Trade or Proprietary Name: TORQTECH
Type: ST-DH, CA-DC, CA-DC-O, CA-51F-O
Common Name: Dental handpiece and accessories

2. SUBMITTER NAME AND ADDRESS WITH PHONE/FAX

| | |
|--------------------------|-----------------------------|
| Registration No. 2081055 | Registration No. 3002807636 |
| Initial Distributor: | Manufacturer |
| J. Morita USA, Inc. | J. MORITA MFG. CORP. |
| 9 Mason | 680 Higashihama Minami-cho |
| Irvine, CA 92618 | Fushimi-ku, Kyoto |
| USA | Japan 612-8533 |
| Telephone: 949-581-9600 | +81-75-611-2141 |
| Facsimile: 949-581-9688 | +81-75-605-2354 |

3. CONTACT PERSON

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, D.C. 20005
Telephone: (202) 783-5070
Facsimile: (202) 783-2331

4. DATE SUMMARY PREPARED: December 5, 2010**5. DEVICE CLASSIFICATION/CLASSIFICATION PANEL**

The TORQTECH has been classified as non-exempt Class 1 devices.

Device classification: 21CFR 872.4200
Dental handpiece and accessories

Device classification panel: 872 Dental Devices

6. DEVICE DESCRIPTION/SUBSTANTIAL EQUIVALENCE

DEVICE DESCRIPTION

The TORQTECH device is a dental handpiece to be attached to an electric or air powered dental motor, designed for polishing, grinding, and drilling of teeth/dentures. The device transmits rotational force from the motor to the rotor shaft through a clutch, and the dental burs or reamers chucked on the shaft are able to polish, grind or cut the teeth/dentures of the patient receiving these rotations.

There are two types of the TORQTECH device: one is a "straight" linear model (Model ST-DH) while the other is angled and geared (Models CA-DC, CA-DC-O, and CA-5IF-O). The geared models vary based on angle and rotation due to the gear between the clutch and rotor shaft. An optional headlight is available, fed through the light-guide from the motor portion.

SUBSTANTIAL EQUIVALENCE

The TORQTECH and its predicate devices have similar general intended uses, similar principles of operation, and similar technological characteristics. Although there are minor differences in the characteristics of the TORQTECH and its predicate devices, these differences do not raise new questions of safety or effectiveness.

The TORQTECH is substantially equivalent to the following devices:

- (1) Kaltenbach & Voight GmbH's "INTRAmatic," "INTRAcompact," and "GENTLEpower" (K#080677) for purposes of performance characteristics; and
- (2) J. Morita Manufacturing Corp.'s own "Twinpower Turbine" handpiece (K#061701) for purposes of biocompatibility of materials
- (3) J. Morita Manufacturing Corp.'s own "AR Spray" (included as part of K#070074) and KAVO "KavoQuattrocare" spray (K#012308) for purposes of the LS Spray that is included with the TORQTECH device.

Two charts identifying the specific characteristics of these various devices appear below:

| Technological Characteristics of Handpiece | Comparison result | |
|--|-------------------|-----------|
| | K080677 | K061701 |
| Indication for use | Similar | — |
| Target population | Identical | — |
| Design | Similar | — |
| Materials | Unknown | Identical |
| Performance | Similar | — |
| Sterility | Similar | Similar |
| Biocompatibility | Unknown | Identical |
| Mechanical safety | Similar | — |
| Chemical safety | Similar | Identical |
| Anatomical sites | Similar | — |
| Human factors | Similar | — |
| Energy used and/or delivered | Similar | — |
| Compatibility with environment and other devices | Similar | — |
| Where used | Identical | — |
| Standards met | Unknown | — |
| Electrical safety | N/A | — |
| Thermal safety | Unknown | — |

The information above demonstrates that the TORQTECH device is substantially equivalent to the predicate device K#080677 in technological characteristics and is substantially equivalent to K#061701 in regard to materials.

The table below demonstrates that the LS spray included with the TORQTECH is substantially equivalent to the sprays authorized in K#070074 and K#012308.

| Name | LS spray | AR spray K#070074 | KAVO QUATTROcare spray K#012308 | Comparison result |
|-----------------|---------------------------------|----------------------|---------------------------------------|----------------------|
| Intended use | Lubrication | Lubrication | Lubrication | Same |
| Materials 1 | Fatty acid ester Mineral oil | Mineral oil | Fatty acid ester oil Mineral oil | Similar |
| Materials 2 | Propane Butane Isobutane | Propane Butane | Propane Butane Isobutane | Similar |

7. INDICATIONS FOR USE

TORQTECH transmits rotation of the motor to dental burs and reamers which cut or grind teeth or dentures with the same or transformed rotation

8. SUMMARY OF NON-CLINICAL TESTING

The TORQTECH was developed and tested in accordance with the following standards:

ISO 7785-2:1995 (dental handpieces – Part 2: straight and geared angle handpieces)

ISO 3964 (dental handpieces – coupling dimensions)

ISO 14971:2007 (medical devices – application of risk management to medical devices)

ISO 10993-1:2003 (biological evaluation of medical devices -- Part 1: evaluation and testing)

ISO 10993-5:2009 (biological evaluation: test for in vitro cytotoxicity)

ISO 10993-12:2007 (biological evaluation: sample preparation and reference materials)

ISO 17664:2004 (information to be provided by the manufacturer for the processing of resterilizable medical devices)

EN 980:2008 (graphical symbols for use in the labeling of medical devices)

EN 1041:2008 (information supplied by the manufacturer with medical devices)

The spray used with the TORQTECH device is considered a mucosal contacting substance of less than 24 hour duration under Annex A of ISO 10993-1: 2009. Results of sensitization and irritation testing under ISO 10993-1 showed the spray to not cause sensitization and that it is not an irritant. The cytotoxicity test results under ISO 10993-1, combined with risk analysis under ISO 14971:2007, demonstrate that the spray is suitable for the clinical application. Finally, with respect to the propellants in the spray, the same gases have been cleared for use in the Kavo predicate device K#012308.

9. **SUMMARY OF CLINICAL TESTING**

No clinical tests were performed for the TORQTECH device.

10. **CONCLUSION**

The information above demonstrates that the TORQTECH device is substantially equivalent to the predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Attorney
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1425 K Street N.W., Suite 1100
Washington, District of Columbia 20005

JAN 20 2012

Re: K103697
Trade/Device Name: TORQTECH
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EGS
Dated: January 12, 2012
Received: January 13, 2012

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Mr. Barritt

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "A. D. Watson" followed by a stylized flourish.

Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number: Unknown

Device Name: TORQTECH

Indications for Use:

TORQTECH transmits rotation of the motor to dental burs and reamers which cut or grind teeth or dentures with the same or transformed rotation.

Prescription Use ☒ AND/OR
(Part21CFR801 Subpart D)

Over-The-Counter Use
(Part21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K103697